

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the Effectiveness of Dimeticone Lotion and 1% Permethrin Shampoo for the Treatment of Head Lice in Clients to Health Centers

Protocol summary

Study aim

Determination of the Effectiveness of Dimethicone Lotion in Comparison with Shampoo Permethrin 1% in the Treatment of Head Lice in Clients to Health Care Centers in Ardabil City in 2017.

Design

A controlled, parallel-group, open-label, randomized, phase 3 clinical trial with 100 patients. Randomization is carried out using an online table of random numbers.

Settings and conduct

In this study, 5 health centers will be randomly chosen from those serviced by Ardabil City's health center, and patients will be thoroughly examined for two months with informed consent.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Having a health record in the health centers of Ardabil city 2. People with head lice based on the observation of nit or lice 3. Informed consent to the study. Exclusion criteria: 1. Pregnant people 2. People who are breastfeeding 3. People who have chronic scalp disease 4. People who have used anti-lice products or hair dyes and hair curlers in the last 2 weeks. 5. People who have used any type of treatment to get rid of lice in the last month. 6. People who have had a history of taking antibiotics in the last two weeks

Intervention groups

People with head lice In the intervention group, the lotion was used, and instruction on how to use it properly was given by the research team in training sessions according to the national guidelines. In the control group, the shampoo was used, and instruction on how to use it properly was given by the research team in training sessions according to the national guidelines.

Main outcome variables

According to the volume, length, and type of hair as well as the severity of the infestation, the success rate of treatment with lotion and shampoo for head lice sufferers will be assessed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181209041895N1**

Registration date: **2023-08-23, 1402/06/01**

Registration timing: **retrospective**

Last update: **2023-08-23, 1402/06/01**

Update count: **0**

Registration date

2023-08-23, 1402/06/01

Registrant information

Name

Eslam Moradi-Asl

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 3775

Email address

moradiasl83@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Dimeticone Lotion and 1% Permethrin Shampoo for the Treatment of Head Lice in Clients to Health Centers

Public title

Effect of Dimethicone and Permethrin in the treatment of head lice

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a file in health centers in Ardabil city Lice sufferers based on the observation of nit or lice The informed consent of the individual to study

Exclusion criteria:

Individuals who are pregnant and breastfeeding
Individuals with chronic scalp disease
Individuals who have used anti-lice products or hair dyes and hair curlers in the last 2 weeks.
Individuals who have used any type of treatment to get rid of lice in the last month.
Individuals who have taken antibiotics in the last two weeks

Age

From **6 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

More than 1 sample in each individual

Number of samples in each individual: **1**

One person is chosen for shampoo treatment and one for lotion treatment.

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the randomization list was generated using the website

<https://www.sealedenvelope.com/simple-randomiser/v1/>.

This list contained 50 A codes and 50 B codes. This list was only available to the randomization supervisor in the form of A and B codes. When the patient went to the health center to receive head lice services, he/she received the assigned code by phone from the supervisor. After this stage, the research team provided services to the patients based on the received code.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ardabil University of Medical Sciences

Street address

Health Faculty, Ardabil University of Medical Sciences, Daneshgah Street, Ardabil City

City

Ardabil

Province

Ardabil

Postal code

5618953141

Approval date

2018-12-22, 1397/10/01

Ethics committee reference number

IR.ARUMS.REC.1397.170

Health conditions studied**1****Description of health condition studied**

Pediculosis

ICD-10 code

B85

ICD-10 code description

Pediculosis and phthiriasis

Primary outcomes**1****Description**

hair type, volume, and length, as well as intensity of infestation

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Dimethicone lotion 4% (Sepidaj company) was used, and training on how to use it correctly was provided by the research team specifically and in training classes (2 sessions and 1 hour each session) according to national guidelines.

Category

Treatment - Drugs

2

Description

Control group: Permethrin 1% shampoo (Gilaranco company) was used, and training on how to use it correctly was provided by the research team specifically and in training classes (2 sessions and 1 hour each session) according to national guidelines.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil Health Center

Full name of responsible person

Eslam Moradi-Asl

Street address

Health Faculty, Ardabil University of Medical Sciences,
Daneshgah Street, Ardabil City

City

Ardabil

Province

Ardabil

Postal code

05189-80991

Phone

+98 45 3353 3784

Fax

+98 45 3353 4786

Email

moradiasl83@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Shahab Behloui

Street address

Health Faculty, Ardabil University of Medical Sciences,
Daneshgah Street, Ardabil City

City

Ardabil

Province

Ardabil

Postal code

05189-80991

Phone

+98 45 3353 4776

Fax

+98 45 3353 4757

Email

research@arums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Eslam Moradiasl

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Entomology

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Email

moradiasl83@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Province

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5618953141

Phone

+98 45 3353 3775

Fax

+98 45 3353 2004

Email

moradiasl83@yahoo.com

Email

moradiasl83@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Data that is unrecognizable and public will be expressed as a percentage.

When the data will become available and for how long

It will be published after the study is completed and written.

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

To use the results of this study to prevent disease, it will be published without identifying the participants.

From where data/document is obtainable

Dr. Eslam Moradi-Asl, Health Faculty, Ardabil University of Medical Sciences, Daneshgah Street, Ardabil City.

Email: Moradiasl83@yahoo.com Tel: +98 9143546796

What processes are involved for a request to access data/document

Written Request and Consent of Deputy Research and Technology.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Eslam Moradiasl

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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